

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS**

INFORMED CONSENT ACTION)	
NETWORK,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 1:21-cv-01026
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION,)	
)	
Defendant.)	
)	

ANSWER TO PLAINTIFF'S COMPLAINT

Defendant, the U.S. Food and Drug Administration (“FDA”) by and through undersigned counsel, hereby answers the Complaint (ECF No. 1) (“Complaint”) filed by Plaintiff Informed Consent Action Network (“ICAN”) on November 12, 2021, as follows, in correspondingly numbered paragraphs:

1. Admitted.
2. Admitted.
3. The allegation in the first sentence that FDA publicly released a document titled “CMC Review Memorandum” dated August 21, 2021, is admitted. The remainder of the allegations in the first sentence are denied. By way of further response, FDA avers that it publicly released the CMC Review Memorandum on or about September 17, 2021. The rest of the allegations in this paragraph purport to characterize that memorandum, which speaks for itself. Defendant respectfully refers the Court to the CMC Review Memorandum for a full and accurate statement of its contents. To the extent that Plaintiff’s allegations are inconsistent with the memorandum, this paragraph is denied.

4. This paragraph purports to characterize the CMC Review Memorandum, which speaks for itself. Defendant respectfully refers the Court to the CMC Review Memorandum for a full and accurate statement of its contents. To the extent that Plaintiff's allegations are inconsistent with the memorandum, this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
5. This paragraph consists of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph.
6. Admitted that on October 5, 2021, Plaintiff submitted a FOIA request to FDA, and that the FOIA request states, in part, "Please provide unredacted copies of Table 22, Table 25, and Table 26 in the document titled CMC Review Memorandum dated August 21, 2021." Defendant respectfully refers the Court to Plaintiff's FOIA request for a full and accurate statement of its contents. *See* Compl., Exh. B.1, ECF No. 1-2. The remainder of the first sentence of this paragraph consists of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations in the first sentence of this paragraph. The second sentence of this paragraph (including the footnote) purports to characterize the CMC Review Memorandum, which speaks for itself. Defendant respectfully refers the Court to the CMC Review Memorandum for a full and accurate statement of its contents. To the extent that Plaintiff's allegations are inconsistent with the memorandum, the second sentence of this paragraph (including the footnote) is denied.

7. The allegations in this paragraph sets forth Plaintiff's alleged motivations for its FOIA request about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. The allegations in this paragraph also consist of Plaintiff's opinions rather than facts, Plaintiff's characterization of this action, and Plaintiff's conclusions of law. They do not set forth a claim for relief or aver facts in support of a claim to which a response is required. Furthermore, the allegations in this paragraph consist of "claim[s]" by unnamed "government officials, medical professionals, and public health agencies," as well as activities by unnamed members of the "medical and scientific community and the public," such that Defendant lacks sufficient information to admit or deny.
8. The allegations in this paragraph sets forth Plaintiff's alleged motivations for its FOIA request about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. They do not set forth a claim for relief or aver facts in support of a claim to which a response is required. Furthermore, the allegations in this paragraph consist of Plaintiff's opinions rather than facts, such that Defendant lacks sufficient information to admit or deny.
9. Admitted that Plaintiff requested expedited processing of its FOIA request. The rest of the allegations in this paragraph purport to characterize Plaintiff's FOIA request, which speaks for itself. Defendant respectfully refers the Court to the FOIA request dated October 5, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. B.1, ECF No. 1-2.
10. Admitted that FDA denied Plaintiff's request for expedited processing. The rest of the allegations in the first sentence of this paragraph purport to characterize FDA's letter to

Plaintiff, which speaks for itself. Defendant respectfully refers the Court to FDA's letter dated October 18, 2021, for a full and accurate statement of its contents. *See Compl. Exh. C, ECF No. 1-5.* The second sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required.

11. This paragraph consists of Plaintiff's characterization of itself about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
12. The allegations in the first sentence are admitted. The second sentence consists of Plaintiff's legal conclusions to which no response is required.
13. This paragraph consists of Plaintiff's legal conclusions regarding jurisdiction and venue, to which no response is required.
14. The allegations in this paragraph purport to characterize an FDA website, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, this paragraph is denied.
15. The allegations in this paragraph purport to characterize an FDA website, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, this paragraph is denied.
16. The allegations in this paragraph consist of Plaintiff's conclusions of law, to which no response is required. The allegations in this paragraph also purport to characterize a statute, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the statute, this paragraph is denied.
17. The allegations in this paragraph purport to characterize an FDA website, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, this

paragraph is denied. Defendant respectfully refers the Court to the cited website for a full and accurate statement of its contents.

18. Admitted.
19. The allegation in the first sentence that FDA publicly released a document titled “CMC Review Memorandum” dated August 21, 2021, is admitted. The remainder of the allegations in the first sentence are denied. By way of further response, FDA avers that it publicly released the “CMC Review Memorandum” on or about September 17, 2021. The remainder of the allegations in this paragraph purport to characterize the CMC Review Memorandum, which speaks for itself. Defendant respectfully refers the Court to the CMC Review Memorandum for a full and accurate statement of its contents. To the extent that Plaintiff’s allegations are inconsistent with the memorandum, this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
20. The allegations in this paragraph purport to characterize websites by the Centers for Disease Control and Prevention, the World Health Organization, Washington State Department of Health, and the State of New Jersey, as well as an article by wlns.com, which speak for themselves. To the extent that Plaintiff’s allegations are inconsistent with the website and the article, this paragraph is denied. Defendant respectfully refers the Court to the cited websites and article for a full and accurate statement of their contents.
21. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff’s allegations are inconsistent with the news

release, this paragraph is denied. Defendant respectfully refers the Court to the cited news release for a full and accurate statement of its contents.

22. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, this paragraph is denied. Defendant respectfully refers the Court to the cited news release for a full and accurate statement of its contents.
23. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, this paragraph is denied. Defendant respectfully refers the Court to the cited news release for a full and accurate statement of its contents.
24. The allegations in this paragraph purport to characterize an article by CBS News, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the article, this paragraph is denied. Defendant respectfully refers the Court to the cited article for a full and accurate statement of its contents.
25. The allegations in the first sentence of this paragraph purport to characterize blog posts by the BMJ, a letter from fifteen Senators to FDA, and an article by the Washington Times, which speak for themselves. To the extent Plaintiff's allegations are inconsistent with the blog posts, letter, and article, the first sentence of this paragraph is denied. Defendant respectfully refers the Court to the cited blog posts, letter, and article for a full and accurate statement of their contents. The second sentence is denied.
26. The allegations in this paragraph purport to characterize articles by the National Law Review, Associated Press, Forbes, CNN, Yahoo! News, CNBC, CBS, ABC News, KPBS, Reuters, The Hill, University Business, NBC News, NPR, Patch, NBC New

York, nj.com, Mercury News, The New York Times, Boston Herald, Mississippi Free Press, Huffington Post, The Advocate, and the Los Angeles Times, as well as websites by the White House, New York City, CVS, the University of Colorado—Boulder, the University of California—Berkeley, Harvard University, George Mason University, New York State, California Department of Public Health, and City of Denver, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles, this paragraph is denied. Defendant respectfully refers the Court to the cited articles for a full and accurate statement of their contents. In addition, the paragraph consists of Plaintiff's characterization of alleged “objections” raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

27. The allegations in this paragraph purport to characterize articles by The Hill and CNN, websites by the White House and the Occupational Safety and Health Administration, an interim final rule published in the Federal Register, and a bill, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles, websites, the interim final rule, and the bill, this paragraph is denied. Defendant respectfully refers the Court to the cited articles, websites, and interim final rule for a full and accurate statement of their contents.
28. The allegations in this paragraph purport to characterize two New York state senate bills and articles by nj.com and eastcountytoday.com, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the bills and articles, this paragraph is denied. Defendant respectfully refers the Court to the cited bills and articles for a full and accurate statement of their contents.

29. The allegations in this paragraph purport to characterize an article from USA Today, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the article, this paragraph is denied. Defendant respectfully refers the Court to the cited article for a full and accurate statement of its contents.
30. The allegations in this paragraph purport to characterize an article by NBC News and a video on YouTube, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the article and video, this paragraph is denied. Defendant respectfully refers the Court to the cited article and video for a full and accurate statement of their contents.
31. Admitted that Plaintiff submitted a FOIA request to FDA on October 5, 2021. Furthermore, an allegation in the first sentence of this paragraph purports to characterize an FDA website, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, this allegation in the first sentence of this paragraph is denied. Defendants respectfully refers the Court to the cited website for a full and accurate statement of its contents. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information. The remaining allegations in the first sentence of this paragraph consist of Plaintiff's characterization of itself and its work, as well as its motivation for submitting the FOIA request to FDA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in the first sentence of this paragraph. The second sentence of this paragraph purports to characterize Plaintiff's FOIA request, which speaks for itself. Defendant respectfully refers the Court to the FOIA request dated October 5, 2021, for a full and accurate statement of its contents. *See Compl.*

Exh. B.1, ECF No. 1-2. To the extent that Plaintiff's allegations are inconsistent with its FOIA request, the allegations in the second sentence of this paragraph are denied. The allegations in the first two sentences of footnote 34 are admitted. By way of further response, Defendant avers that FDA updated its web posting of records related to the Pfizer-BioNTech COVID-19 vaccine, including the CMC Review Memorandum, on or about October 12, 2021, and most recently on or about December 3, 2021. The allegations in the third sentence of footnote 34 consist of Plaintiff's characterization of this action, opinions rather than facts, and conclusions of law, to which no response is required. To the extent a response is required, the third sentence of footnote 34 is denied.

32. The allegations in this paragraph purport to characterize a FOIA Request Confirmation, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the FOIA Request Confirmation, this paragraph is denied. Defendant respectfully refers the Court to the FOIA Request Confirmation dated October 5, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. B.2, ECF No. 1-3.
33. Admitted. Defendant respectfully refers the Court to the letter from FDA to Plaintiff dated October 12, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. B.3, ECF No. 1-4.
34. Admitted. Defendant respectfully refers the Court to the FOIA request dated October 5, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. B.1, ECF No. 1-2.
35. Admitted that FDA denied Plaintiff's request for expedited processing on October 18, 2021. The rest of the allegations in this paragraph purport to characterize FDA's letter

to Plaintiff, which speaks for itself. Defendant respectfully refers the Court to FDA's letter dated October 18, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. C, ECF No. 1-5. To the extent that Plaintiff's allegations are inconsistent with FDA's letter dated October 18, 2021, this paragraph is denied.

36. This paragraph sets forth Plaintiff's conclusions of law, to which no response is required. The allegations in this paragraph also purport to characterize a statute, which speaks for itself. To the extent that a response is required, FDA denies the allegations in this paragraph.
37. Admitted that Plaintiff stated in its FOIA request that it was "primarily engaged in disseminating information" and that Plaintiff stated in its FOIA request there is an "urgency to inform the public concerning actual or alleged Federal Government activity." The rest of the allegations in the first sentence of this paragraph are Plaintiff's characterization of its FOIA request, to which no response is required. Defendant respectfully refers the Court to the FOIA request dated October 5, 2021, for a full and accurate statement of its contents. *See* Compl. Exh. B.1, ECF No. 1-2. To the extent that Plaintiff's allegations are inconsistent with the FOIA request, the first sentence of this paragraph is denied. As for the second sentence of this paragraph, admitted that FDA stated in its letter to Plaintiff dated October 18, 2021, that Plaintiff had not "demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual" and that Plaintiff had not demonstrated that "there exists an urgency to inform the public concerning actual or alleged Federal Government activity." The rest of the allegations in the second sentence of this paragraph are Plaintiff's characterization of FDA's letter to Plaintiff, to which no response is required.

Defendant respectfully refers the Court to FDA's letter dated October 18, 2021, for a full and accurate statement of its contents. *See Compl. Exh. C, ECF No. 1-5.* To the extent that Plaintiff's allegations are inconsistent with FDA's letter dated October 18, 2021, the second sentence of this paragraph is denied. The third sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied.

38. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied.
39. This paragraph sets forth Plaintiff's conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. Furthermore, the allegations in this paragraph purport to characterize a judicial opinion, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the judicial opinion, this paragraph is denied. Defendant respectfully refers the Court to the cited judicial opinion for a full and accurate statement of its contents.
40. The first sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied. The second sentence of this paragraph purports to characterize the publicly released version of the CMC Review Memorandum, which speaks for itself. To the extent that the allegations in the second sentence of this paragraph are inconsistent with that memorandum, these allegations are denied. Defendant respectfully refers the Court to the CMC Memorandum for a full and accurate statement of its contents. By way of

further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.

41. This paragraph consists of Plaintiff's characterization of alleged "objections" raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. Furthermore, the allegations in this paragraph purport to characterize articles by the National Law Review, Associated Press, Forbes, CNN, Yahoo! News, CNBC, CBS, ABC News, KPBS, Reuters, The Hill, University Business, NBC News, NPR, Patch, NBC New York, nj.com, Mercury News, The New York Times, Boston Herald, Mississippi Free Press, Huffington Post, The Advocate, and the Los Angeles Times, as well as websites by the White House, New York City, CVS, the University of Colorado—Boulder, the University of California—Berkeley, Harvard University, George Mason University, New York State, California Department of Public Health, and City of Denver, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles and websites, this paragraph is denied. Defendant respectfully refers the Court to the cited articles and websites for a full and accurate statement of their contents. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
42. The allegations in the first two sentences of this paragraph consist of Plaintiff's opinions rather than facts, Plaintiff's speculation, Plaintiff's characterization of this action, and Plaintiff's conclusions of law. They do not set forth a claim for relief or aver facts in support of a claim to which a response is required. To the extent a response is required, the allegations in the first and second sentence of this paragraph are denied. The

allegation in the third sentence of this paragraph that FDA lifted redactions in the CMC Review Memorandum after Plaintiff submitted its FOIA request is admitted. The remainder of the third sentence of this paragraph, including Plaintiff's characterization of the redaction as "hid[ing]" information is denied. By way of further response, Defendant avers that FDA updated its web posting of records related to the Pfizer-BioNTech COVID-19 vaccine, including the CMC Review Memorandum, on or about October 12, 2021, and most recently on or about December 3, 2021. The allegations in the fourth sentence this paragraph consist of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the fourth sentence of this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.

43. The first sentence of this paragraph purports to characterize a website by the American Medical Association, which speaks for itself. To the extent Plaintiff's allegations are inconsistent with the website, this sentence is denied. Defendant respectfully refers the Court to the cited website for a full and accurate statement of its contents. The remainder of the allegations in this paragraph consist of Plaintiff's opinions rather than facts and Plaintiff's characterization of this action. They do not set forth a claim for relief or aver facts in support of a claim to which a response is required. To the extent a response is required, this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information, and FDA promotes the importance of informed consent on its website. *See,*

e.g., FDA, Informed Consent for Clinical Trials, https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials.”).

44. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied.
45. This paragraph consists of Plaintiff's characterization of itself, its work, and its future actions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph.
46. This paragraph consists of Plaintiff's conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. This paragraph also purports to characterize a statute, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the statute, this paragraph is denied. Defendant respectfully refers the Court to the cited statute for a full and accurate statement of its contents.

The remaining paragraphs of the Complaint contain Plaintiff's requested relief, to which no response is required. To the extent a response is required, Defendant denies the allegations contained in the remaining paragraphs of the Complaint and further avers that Plaintiff is not entitled to any relief.

Defendant hereby denies all allegations in the Complaint not expressly admitted or denied.

DEFENSE

1. Some or all of the requested records or information may be exempt from disclosure, in whole or in part, under 5 U.S.C. § 552(b).

Dated: December 13, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General
Civil Division

ELIZABETH J. SHAPIRO
Deputy Director
Federal Programs Branch

/s/ Courtney D. Enlow
COURTNEY D. ENLOW (NC Bar No. 46578)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Room 12102
Washington, D.C. 20005
Tel: (202) 616-8467
Email: courtney.d.enlow@usdoj.gov

Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2021, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Western District of Texas using the CM/ECF filing system.

/s/ Courtney D. Enlow

COURTNEY D. ENLOW

Trial Attorney

United States Department of Justice

Civil Division, Federal Programs Branch

1100 L Street, N.W.

Room 12102

Washington, D.C. 20005

Tel: (202) 616-8467

Email: courtney.d.enlow@usdoj.gov